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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/351,985 07/12/99 BRAUN

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021003
BAKER & BOTTS
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NEW YORK NY 10112

HM12/0815

EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/351,985

Applicant(s)

BRAUN ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: .

DETAILED ACTION

Claim Rejections 35 U.S.C. – 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The term "deep-frozen" in claims 1, 6 and 12 is a relative term which renders the claim indefinite. The term "deep-frozen" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are indefinite as to the freezing temperature employed for freezing the thrombocytes or thrombocyte fragment.
4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd.

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App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation at least 10^4 thrombocytes per ml, and the claim also recites recitation at least 10^5 thrombocytes per ml, which is the narrower statement of the range/limitation.

5. Claim 10 provides for the use of thrombocytes or thrombocyte fragment containing growth factors, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections 35 U.S.C. - 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1–20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patat et al. (US 5,589,462) in view of Delmas (US 5,618,663), Dimoudis et al. (CA abstract, AN 1996:313895, 1996) and Goodrich et al. (WO 91/17655, IDS of Oct. 7, 1999).

Patat et al. teaches a medicinal product for topical application for the promotion of wound healing, which comprising frozen growth factor containing thrombocytes. See, particularly, the abstract, column 1, line 49 bridging column 2, line 7, column 2, line 21 bridging column 3, line 14 and column 6, lines 24–31. The freezing temperature is below -15°C . See, particularly, column 4, lines 31–36. The reference teaches that thrombocytes are known to be one of the principal sources of growth factors. See, column 1, lines 54–64. Growth factors along with other components such as fibronectin, thrombin and collagen are known to be useful for promoting wound healing. See, particularly, column 1, lines 5–41. The reference teaches that the platelet (thrombocyte) enriched plasma contains about 10^8 to 5×10^8 thrombocytes. See, column 4, lines 13–29. The reference further teaches that the medicinal product contains other components normally present in a platelet extract, e.g., protein, fibrinogen. See, column 3, lines 6–24.

The reference does not expressly teach inactivation of viruses with the thrombocytes or the employment of additional epithelial cells and/or keratinocytes and/or embryonic and/or fetal cells and/or liposomes and lyophilization of thrombocytes.

However, Delmas teaches inactivation of viruses with a thrombocyte products for healing. See, particularly, column 6, lines 35–46. Goodrich et al. teach lyophilization of platelets and cell-like matter from human blood including bioadhesive material in compositions for therapeutic purpose. See the abstract and summary. The reference teaches that other kind of cells

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can be used therein. See, page 7, lines 7-11. Dimoudis et al. teach that epithelial cell is known to be useful in wound healing composition. See the title and the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to modify the platelet factor enriched thrombocyte compositions of Patat et al. with the inactivation of viruses present with thrombocyte taught by Delmas, and lyophilization taught by Goodrich and by the addition of other known wound healing components such as epithelial cell.

A person of ordinary skill in the art would have been motivated to modify the platelet factor enriched thrombocyte compositions of Patat et al. with the inactivation of viruses present with thrombocyte taught by Delmas, and lyophilization taught by Goodrich and by the addition of other known wound healing components such as epithelial cell because inactivation of viruses is well known to be necessary for any topical wound healing composition to avoid any possible transmission of disease. The addition of epithelial cells is seen to be obvious since epithelial cells are known to be useful in would healing composition. A person of ordinary skill in the art would have been motivated to use lyophilization method because this method is known to provide reconstitutable platelets, which may be stored at high storage temperature. (See, page 3, lines 17-21 in Goodrich).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

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July 19, 2000


MINNA MOEZIE
PRIMARY EXAMINER